REMARKS

Applicants reserve the right to prosecute non-elected subject matter in subsequent divisional applications.

I. Pending claims

Claims 24-43 are pending and claims 1-23 have been canceled. Justification for the amendments is as follows. Amendment of the claims and addition of the new claims serve to further clarify the subject matter which applicants consider to be the invention. New claims 26-32 and 34 are drawn to polynucleotides, expression vectors, host cells, and methods of producing a polypeptide and replace original claims 3-12, while new claims 24-25, 33, and 38-39 are drawn to polypeptides, antibodies, and compositions comprising the polypeptide and replace claims 1-2 and 13-14. New claims 35-37 are drawn to methods of detection of polynucleotides and replace claims 22-23. New claims 40 and 41, which are drawn to methods of identifying compounds that bind to and modulate the activity of the polypeptide, are supported in the Specification at, e.g., page 43, line 26 through page 44, line 9; and Example XIV at page 56. New claims 42 and 43, drawn to methods of testing compounds for effectiveness in altering polynucleotide expression and for toxicity, are supported in the Specification at, e.g., page 37, lines 20-30; page 40, line 29 through page 41, line 8; and page 42, lines 14-20. No new matter is added by any of these amendments.

II. Restriction Requirement

In the Restriction Requirement, the Examiner requested Applicants to elect one of the following inventions:

Group I (claims 1-13) drawn to a polypeptide, comprising an amino acid sequence set forth in SEQ ID NO:5, a nucleic acid encoding the polypeptide, an expression vector, a host cell and a method for producing the polypeptide.

Group II (claims 1-13) drawn to a polypeptide, comprising an amino acid sequence set forth in SEQ ID NO:1, a nucleic acid encoding the polypeptide, an expression vector, a host cell and a method for producing the polypeptide.

Group III (claims 1-13) drawn to a polypeptide, comprising an amino acid sequence set forth in SEQ ID NO:2, a nucleic acid encoding the polypeptide, an expression vector, a host cell and a method for producing the polypeptide.

Group IV (claims 1-13) drawn to a polypeptide, comprising an amino acid sequence set forth in SEQ ID NO:3, a nucleic acid encoding the polypeptide, an expression vector, a host cell and a method for producing the polypeptide.

Group V (claims 1-13) drawn to a polypeptide, comprising an amino acid sequence set forth in SEQ ID NO:4, a nucleic acid encoding the polypeptide, an expression vector, a host cell and a method for producing the polypeptide.

Group VI (claim 14) drawn to an antibody to a polypeptide comprising an amino acid sequence set forth in SEQ ID NO:5.

Group VII (claim 14) drawn to an antibody to a polypeptide comprising an amino acid sequence set forth in SEQ ID NO:1.

Group VIII (claim 14) drawn to an antibody to a polypeptide comprising an amino acid sequence set forth in SEQ ID NO:2.

Group IX (claim 14) drawn to an antibody to a polypeptide comprising an amino acid sequence set forth in SEQ ID NO:3.

Group X (claim 14) drawn to an antibody to a polypeptide comprising an amino acid sequence set forth in SEQ ID NO:4.

Group XI (claim 15) drawn to an agonist to a polypeptide comprising an amino acid sequence set forth in SEQ ID NO:5.

Group XII (claim 15) drawn to an agonist to a polypeptide comprising an amino acid sequence set forth in SEQ ID NO:1.

Group XIII (claim 15) drawn to an agonist to a polypeptide comprising an amino acid sequence set forth in SEQ ID NO:2.

Group XIV (claim 15) drawn to an agonist to a polypeptide comprising an amino acid sequence set forth in SEQ ID NO:3.

Group XV (claim 15) drawn to an agonist to a polypeptide comprising an amino acid sequence set forth in SEQ ID NO:4.

Group VXI (claim 16), drawn to an antagonist of the polypeptide comprising an amino acid sequence set forth in SEQ ID NO:5.

Group VXII (claim 16), drawn to an antagonist of the polypeptide comprising an amino acid sequence set forth in SEQ ID NO:1.

Group VXIII (claim 16), drawn to an antagonist of the polypeptide comprising an amino acid sequence set forth in SEQ ID NO:2.

Group XIX (claim 16), drawn to an antagonist of the polypeptide comprising an amino acid sequence set forth in SEQ ID NO:3.

Group XX (claim 16), drawn to an antagonist of the polypeptide comprising an amino acid sequence set forth in SEQ ID NO:4.

Groups XXI to XXV (claims 17, 19, 21) drawn to a method of treatment comprising administering the polypeptide comprising an amino acid sequence set forth in SEQ ID NO:1-5.

Groups XXVI to XXX (18, 20), drawn to a method of treatment comprising administering an antagonist to the polypeptide comprising an amino acid sequence set forth in SEQ ID NO:1-5.

Groups XXXI to XXXV (claims 22-23), drawn to a method for detecting a polynucleotide encoding the polypeptide comprising an amino acid sequence set forth in SEQ ID NO:1-5.

Group Number	Original Claims	New Claims
Groups I to V (claims 1-13), drawn to a polypeptide, comprising an amino acid sequence set forth in SEQ ID NO:1-5, a nucleic acid encoding the polypeptide, an expression vector, a host cell and a method for producing the polypeptide.	1	24-25
	2	24-25
	3	26
	4	26
	5	26
	6	34
	7	34
	8	34
	9	34
	10	29
	11	30

	12	31, 32
	13	38, 39
Groups VI to X (claim 14), drawn to an antibody to a polypeptide comprising an amino acid sequence set forth in SEQ ID NO:1-5.	14	33
Groups XI to VX (claim 15), drawn to an agonist of the polypeptide comprising an amino acid sequence set forth in SEQ ID NO:1-5.	15	-
Groups XVI to XX (claim 16), drawn to an antagonist of the polypeptide comprising an amino acid sequence set forth in SEQ ID NO:1-5.	16	-
Groups XXI to XXV (claims 17, 19, 21) drawn to a method of treatment comprising administering the polypeptide comprising an amino acid sequence set forth in SEQ ID NO:1-5.	17	-
	19	-
	21	-
Groups XXVI to XXX (18, 20), drawn to a method of treatment comprising administering an antagonist to the polypeptide comprising an amino acid sequence set forth in SEQ ID NO:1-5.	18	-
	20	-
Groups XXXI to XXXV (claims 22-23), drawn to a method for detecting a polynucleotide encoding the polypeptide comprising an amino acid sequence set forth in SEQ ID NO:1-5.	22	35-36
	23	37

Applicants hereby elect, with traverse, to prosecute Group IV, which includes claims 24-32, 34, and 38-39 (replacing original claims 1-13), drawn to a polypeptide, comprising an amino acid sequence set forth in SEQ ID NO:3, a nucleic acid encoding the polypeptide, an expression vector, a host cell, and a method for producing the polypeptide.

Applicants reserve the right to prosecute the subject matter of non-elected claims in subsequent divisional applications. Applicants traverse both the restriction requirement and the obligation to elect a single sequence for prosecution, which were imposed in the Restriction Requirement mailed June 30, 2003 for at least the following reasons.

Applicants note that the invention encompassed by claims 35-37 (replacing claims 22 and 23 of Groups XXXI-XXV), claims 40-41, and claims 42-43 are drawn to methods of use of the polypeptides and polynucleotides of Groups I-V, and should be examined together. These method claims recite a product (i.e., a polynucleotide or a polypeptide), which is of the same scope as the claimed polypeptides and polynucleotides being searched by the Examiner. Therefore, it would not be an undue burden on the Examiner to examine these method claims since the searches for the claimed

polypeptides and polynucleotides and these method claims would substantially overlap.

In the present case, unity of invention exists among all of Applicants' claims. In Applicants' method claims (31-32, 35-37, and 40-43), the claimed sequences serve as either the product of the claimed method (claims 31 and 32, drawn to a method of polypeptide production) and/or as a reagent for performing the method (claims 40 and 41, drawn, respectively, to methods of screening for compounds which specifically bind, or compounds which modulate the activity of, a polypeptide of claim 24; and claims 35-37, 42, and 43, drawn, respectively, to methods of detecting a target polynucleotide in a sample, a method of screening for compounds which alter the expression of a target polynucleotide, and a method for assessing toxicity of a test compound).

Therefore, the claimed polypeptide and polynucleotide sequences are corresponding technical features which are common to all of Applicants' claims, and which serve to technically interrelate them.

In sum, the claimed polypeptide sequences and the claimed polynucleotide sequences which encode them are corresponding technical features which are common to all of Applicants claims, which serve to technically interrelate all of Applicants' claims, and which define the contribution over the prior art made by each of them. Thus, Applicants' claims are linked to form a single general inventive concept, and Applicants are therefore entitled to prosecute all of their pending claims in a single national stage application. Withdrawal of the restriction requirement in the present case and examination of the methods claims together with the composition claims from which they depend is therefore respectfully requested.

In addition, the method claims 35-37 and 40-43 are entitled to rejoinder upon allowance of a product claim per the Commissioner's Notice in the Official Gazette of March 26, 1996, entitled "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)" which sets forth the rules, upon allowance of a product claim, for rejoinder of process claims covering the same scope of products. See also M.P.E.P. 821.04 as follows.

> Where product and process claims drawn to independent and distinct inventions are presented in the same application, applicant may be called upon under 35 U.S.C. 121 to elect claims to either the product or process. . . The claims to the nonelected invention will be withdrawn from further consideration under 37 C.F.R. 1.142. . . . However, if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the

limitations of the allowable product claim will be rejoined.

The Election of Species Requirement

Applicants elect, with traverse, to prosecute claims to the polynucleotide sequences encoding the polypeptide sequence of SEQ ID NO:3, which sequences include SEQ ID NO:8, as well as claims to the polypeptide sequence of SEQ ID NO:3. The polypeptide sequence of SEQ ID NO:3 and the polynucleotide sequence of SEQ ID NO:8 read on claims 24-32, 34, and 38-39. Applicants traverse the Election of Species Requirement for at least the following reasons.

The Examiner's attention is directed to the Patent Office's own requirements for Markush practice, set forth in the 8th edition of the M.P.E.P. (February 2003) at § 803.02 regarding restriction requirements in Markush-type claims:

PRACTICE RE MARKUSH-TYPE CLAIMS

> If the members of the Markush group are **sufficiently few in number or so closely related** that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction.
>
> Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), **it is improper for the Office to refuse to examine that which applicants regard as their invention**, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, **unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility**.
>
> This subsection deals with Markush-type generic claims which include a plurality of alternatively usable substances or members. In most cases, a recitation by enumeration is used because there is no appropriate or true generic language. A Markush-type claim can include independent and distinct inventions. This is true where two or more of the members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. 103 with respect to the other member(s). In applications containing claims of that nature, **the examiner may**

require a provisional election of a single species prior to examination on the merits. The provisional election will be given effect in the event that the Markush-type claim should be found not allowable. Following election, the Markush-type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. If the Markush-type claim is not allowable over the prior art, examination will be limited to the Markush-type claim and claims to the elected species, with claims drawn to species patentably distinct from the elected species held withdrawn from further consideration.

As an example, in the case of an application with a Markush-type claim drawn to the compound C-R, wherein R is a radical selected from the group consisting of A, B, C, D, and E, the examiner may require a provisional election of a single species, CA, CB, CC, CD, or CE. The Markush-type claim would then be examined fully with respect to the elected species and any species considered to be clearly unpatentable over the elected species. If on examination the elected species is found to be anticipated or rendered obvious by prior art, the Markush-type claim and claims to the elected species shall be rejected, and claims to the nonelected species would be held withdrawn from further consideration. As in the prevailing practice, a second action on the rejected claims would be made final.

On the other hand, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a nonelected species, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. The prior art search, however, will not be extended unnecessarily to cover all nonelected species. Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection, as by amending the Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined. The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markush-type claim, the claim will be rejected and the action made final. Amendments submitted after the final rejection further restricting the scope of the claim may be denied entry. [emphasis added]

As can be seen from the above, it is clear that the present Restriction Requirement does not meet the Patent Office's own requirements.

First, if the number of "members of the Markush group are **sufficiently few in number or so closely related** that a search and examination of the entire claim can be made without serious burden, the examiner must examine all claims on the merits, even though they are directed to independent and distinct inventions. **In such a case, the examiner will not follow the procedure described below and will not require restriction.**" Withdrawal of the restriction requirement as between the specific

sequences each in the claims is required on that basis alone.

Second, "**it is improper for the Office to refuse to examine that which applicants regard as their invention**, unless the subject matter in a claim lacks unity of invention. ... Broadly, **unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility**." Clearly, the sequences of the instant invention share both a common utility and structural homology, based on their classification as human cell cycle regulation proteins.

Third, even if the claims could be considered to be "Markush-type generic claims which include a plurality of alternatively usable substances or members," it is further noted that the M.P.E.P states that "A Markush-type claim can include independent and distinct inventions. This is true where two or more of the members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. 103 with respect to the other member(s). In applications containing claims of that nature, **the examiner may require a provisional election of a single species** prior to examination on the merits." This clearly applies in the present case.

Therefore, it is respectfully submitted that, upon searching and examining SEQ ID NO:3 and SEQ ID NO:8 and finding no prior art over which neither SEQ ID NO:3 nor SEQ ID NO:8 can be rejected, the Examiner must extend the search of the Markush-type claim to include the four additional non-elected species.

CONCLUSION

In light of the above amendments and remarks, Applicants submit that the present application is fully in condition for allowance, and request that the Examiner withdraw the outstanding objections/rejections. Early notice to that effect is earnestly solicited.

If the Examiner contemplates other action, or if a telephone conference would expedite allowance of the claims, Applicants invite the Examiner to contact the undersigned at the number listed below.

Applicants believe that no fee is due with this communication. However, if the USPTO determines that a fee is due, the Commissioner is hereby authorized to charge Deposit Account No. **09-0108.**

Respectfully submitted,

INCYTE CORPORATION

Date: July 30, 2003

Gina C. Nellesen
Reg. No. 52,062
Direct Dial Telephone: (650) 843-7342

Date: July 30, 2003

Barrie D. Greene
Reg. No. 46,740
Direct Dial Telephone: (650) 621-7576

Customer No.: 27904
3160 Porter Drive
Palo Alto, California 94304
Phone: (650) 855-0555
Fax: (650) 849-8886